GAMBRO Renal Products

510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectivencss has been submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document are accurate and complete to the best of Gambro Renal Product's knowledge.

SPONSOR
GAMBRO RENAL PRODUCTS
REGULATORY AFFAIRS
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LAKEWOOD, CO 80401

CONTACT
Kae Miller
303.222.6724

DEVICE NAME INFORMATION

Proprietary Name:	Molecular Adsorbent Recirculating System (MARS®)
Common/Usual Name:	Apparatus, Hemoperfusion, Sorbet
Classification Name:	Sorbent Hemoperfusion System

INDICATION
The MARS® is indicated for the treatment of drug overdose and poisonings. The only requirement is that the drug or chemical be dialyzable and bound by charcoal. The MARS® is not indicated for the treatment of chronic liver conditions or as a bridge to liver transplant. Safety and efficacy has not been demonstrated for these indications in controlled, randomized clinical trials.

DEVICE DESCRIPTION
The MARS® is a blood detoxification device comprised of dialyzers, adsorption columns, tubing connectors and a control unit. It is designed for the combined removal of water-soluble low and middle molecular weight substances and albumin bound molecules. The treatment is based on the dialysis of blood against an albumin-containing dialysate solution.

SUBSTANTIAL EQUIVALENCE
The MARS® is substantially equivalent to the predicate devices since the basic features and technologies are similar. The minor differences between the MARS® and the predicate devices raise no new issues of safety and effectiveness.

Signed: Kae Miller

Kae Miller
Regulatory Affairs Manager
Gambro Renal Products

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 16, 2014

Gambro Renal Products, Inc.
Kae Miller
Regulatory Affairs Manager, Americas
10810 W. Collins Avenue
Lakewood, CO 80215

Re: K033262
Trade/Device Name: Molecular Adsorbent Recirculating System (MARS®)
Regulation Number: 21 CFR§ 876.5870
Regulation Name: Sorbent hemoperfusion system
Regulatory Class: III
Product Code: FLD
Dated (Date on orig SE ltr): March 2, 2005
Received (Date on orig SE ltr): March 3, 2005

Dear Kae Miller,

This letter corrects our substantially equivalent letter of May 27, 2005.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K033262

Device Name: Molecular Adsorbent Recirculating System (MARS®)

Indications for Use:

The MARS® is indicated for the treatment of drug overdose and poisonings. The only requirement is that the drug or chemical be dialyzable (in unbound form) and bound by charcoal and/or ion exchange resins.

Contraindication for Use:

The MARS® is not indicated for the treatment of chronic liver disease conditions or as a bridge to liver transplant. Safety and efficacy has not been demonstrated for these indications in controlled, randomized clinical trials.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S
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Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)